EPA High Production Volume [HPV]Tracker

Robust Summary Data Collection Module

USER'S GUIDE

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I. INTRODUCTION:

Thank you for participating in the voluntary Chemical Right-to-Know High Production Volume (HPV) Chemical Challenge Program. The data you submit will help to ensure that government and industry make more sound chemical risk management decisions and that the general public will gain a better understanding of the potential hazards of HPV chemicals.

To ensure that your Robust Summaries are received and routed properly and in a timely fashion, they must be sent to one of the four addresses (regular mail or electronic mail) which follow:

Carol Browner, Administrator
US EPA
P.O. Box 1473
Merrifield, VA 22116
Attn: Chemical Right-to-Know Program

You may submit an electronic version of your submission via email at the following addresses:

hpv.chemrtk@epa.gov
ncic.chemrtk@epa.gov
chemrtk@epa.gov

When submitting electronic files, submit the file in compressed ("zipped") format, if possible. If you have trouble submitting your file via e-mail (for example, if it is too large), you may mail it in on a ZIP disk (100M size only) to the mailing address above.

Note that robust summaries MUST be submitted with a test plan. The test plan may either be submitted to the U.S. HPV Chemical Tracking System site maintained by the American Chemistry Council (ACC) - previously known as the Chemical Manufacturers Association (CMA), or a test plan and robust summary may be sent directly to EPA. Online access to the ACC-maintained site is available at:

http://www.hpvchallenge.com

If you submit your test plan to this site, please mention this in your cover page or other material accompanying your submission of robust summaries to EPA.

II. SYSTEM OVERVIEW

The EPA High Production Volume (HPV) Tracker, Robust Summary Data Collection Module is a user-friendly MS Access database created for use by industry participants in the HPV Challenge Program.

The database may be obtained by downloading the self-extracting file from the EPA Chemical Right-To-Know web site - http://www.epa.gov/opptintr/chemrtk - or installed from individual CD ROM's distributed by EPA.

Minimum system requirements are:

- Windows 95/98 for the operating system
- CD ROM drive
- Minimum 50 MB hard drive space
- 64 RAM
- WinZip or equivalent archive utility
- Internet Browser

III. INSTALLATION:

A. Option #1 - Web Download

1. Define Work Folder

Before downloading, we recommend that you create a work folder on one of your drives to serve as the central repository to download and extract the application files into. Creation of a separate work folder allows quicker access to and easier identification of the application and file(s); and avoids interference with other system files that may have the same or similar identifications.

Example: *drive:*\EPA_Setup

2. Download

A successful download will place the self-extracting installation file "EPA_HPVv1.exe" into the work folder created in the previous step - *drive:*\EPA_Setup.

From Chemical Right-To-Know web page:
http://www.epa.gov/opptintr/chemrtk/index.htm

Click "What's New?" and look for the link that will bring you to the appropriate files.

Follow the steps below and the screen prompts as they guide you through the download and installation process.

• Click on the link to download application.

At the “Save as” dialog box (Figure 1) verify the following:

• “Save in:” block displays work folder created in the “Define Work Folder” instructions above - (i.e. Save in: EPA_Setup)
• “File name:” block displays “EPA_HPVv1.exe”
• Select “Save”

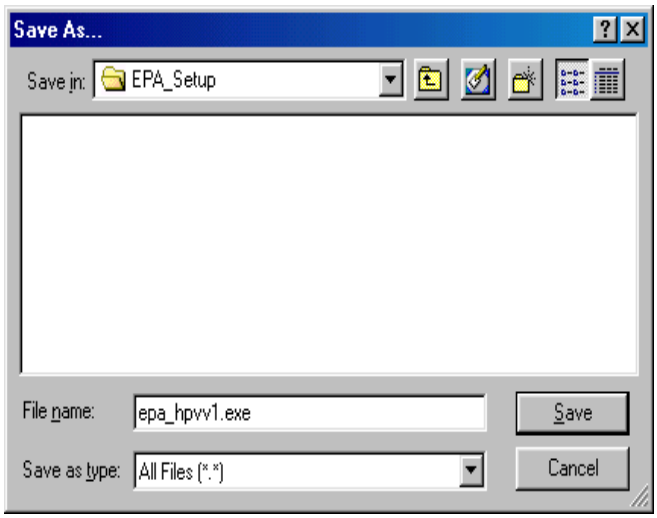

Figure 1

At the “Saving Location” dialog box (Figure 2) -

• Wait until the file download is complete.
• Exit browser.

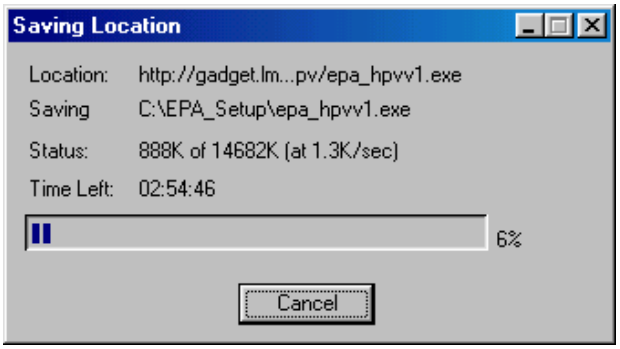

Figure 2

3. Extract Files

From Windows Explorer (Figure 3), go to the work folder defined above - *drive:*\EPA_Setup

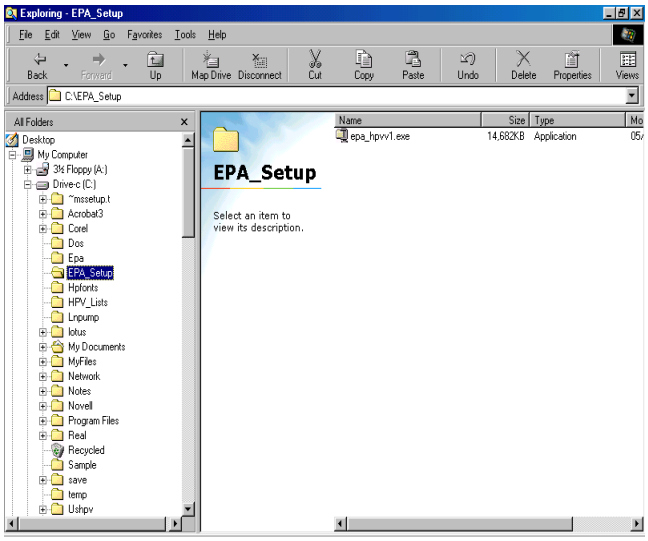

Figure 3

• Double-click on the EPA_HPVv1.exe file

At the "WinZip Self-Extractor" dialog box (Figure 4), verify that "Unzip To Folder:" displays defined work folder *(drive:*\EPA_Setup).

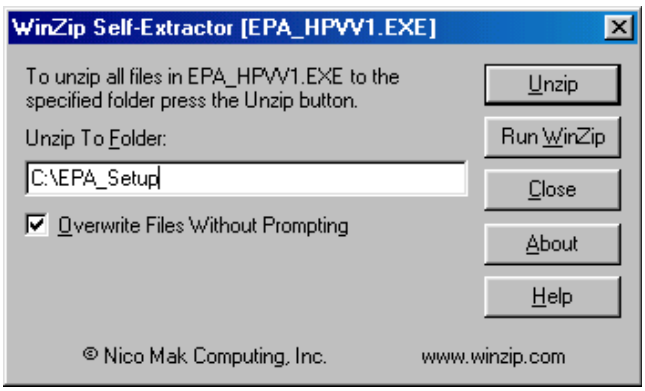

Figure 4

• Select "Unzip" to extract the files into selected folder - *drive*:\EPA_Setup

Successful installation of application will insert 62 files into the selected work folder (Figure 5)- *drive:*\EPA_Setup

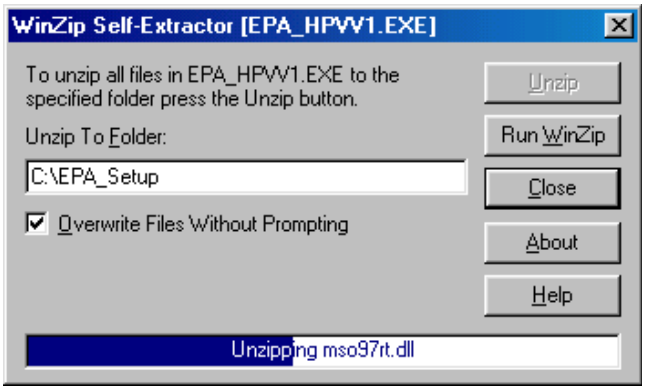

Figure 5

• Select “Ok” / “Close” (Figure 6)

Figure 6

4. Application Setup

Note: If a licensed version of Microsoft Office 97 Professional Edition is already installed on the workstation, execution of “setup.exe” is **NOT** required. To execute the application, create a desktop icon with path set to ***drive:*\EPA_Setup\ EPA_HPVv.mde**. Double-click on the desktop icon. Continue to section IV - General Features of Database - for explanation of database use, features, and functions.

Otherwise continue with setup procedures below:

From the defined work folder, locate the “setup.exe” file.

• Double-click on *drive*:\EPA_Setup\Setup.exe
Accept screen defaults to complete installation - Select:

•“Continue”

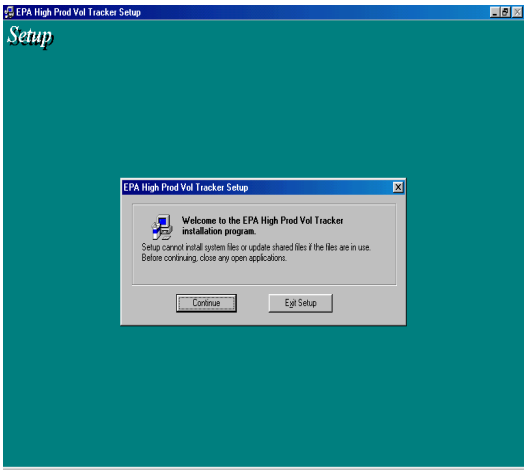

Figure 7

•“OK”

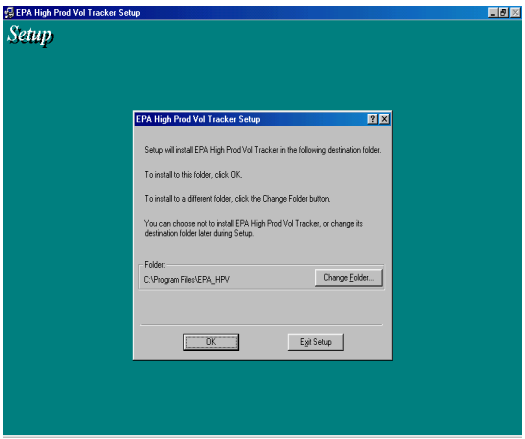

Figure 8

• “Typical Install” - Wait for installation completion.

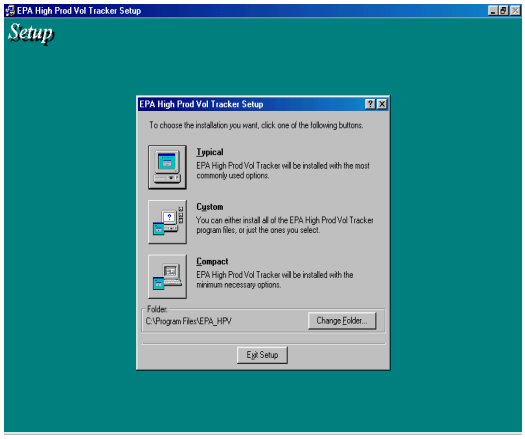

Figure 9

•“OK”

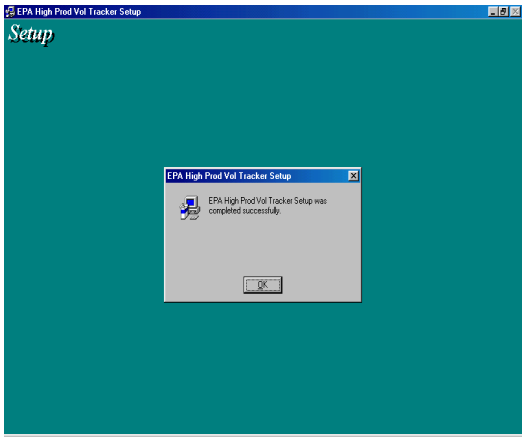

Figure 10

5. Launch Application

For easy access, the application has been added to the windows program menu - C:\Programs\EPA HPV Tracker.

To launch application - Go to: **Start\Programs\EPA HPV Tracker\EPA HPV Tracker**.

Continue to Section IV - General Features of Database - for explanation of database use, features, and functions**.**

B. Option #2 - CD-ROM

Insert CD into drive:

- Double-click on the EPA_HPVv1.exe file
- Extract files into *drive*:\EPA_Setup folder
- Double-click on *drive*:\ EPA_Setup\Setup.exe and follow the screen instructions accepting the same defaults selected in Figures 7-10 above to complete installation.

IV. GENERAL INFORMATION AND DATABASE FEATURES:

The database is designed using MS Access and therefore offers the user-friendly look and feel of any Microsoft application with the use of the basic title bar, menu bar, push-button option selections and status line features throughout the database.

A. Main Menu

The opening page or Main Menu (Figure 11) lists the six database functions accessible from the push buttons shown on the right-hand side of the screen. A brief description of each follows:

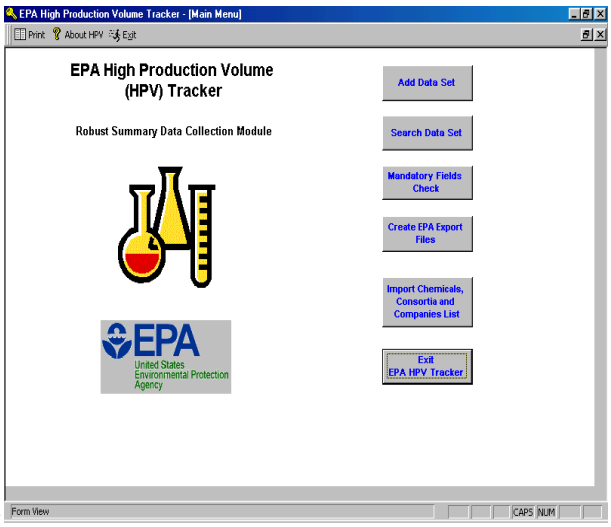

Figure 11

1. Add Data Set - The term “Data Set” is derived from the International Uniform Chemical Information Database (IUCLID) and is defined as the unit in which information is stored within the database. This option allows entry of the unique key identifier, endpoint, and critical identifying information to support the Robust Summary submission. Figures 12 and 13 below illustrate two of the three screens provided in the database for creating your data set.

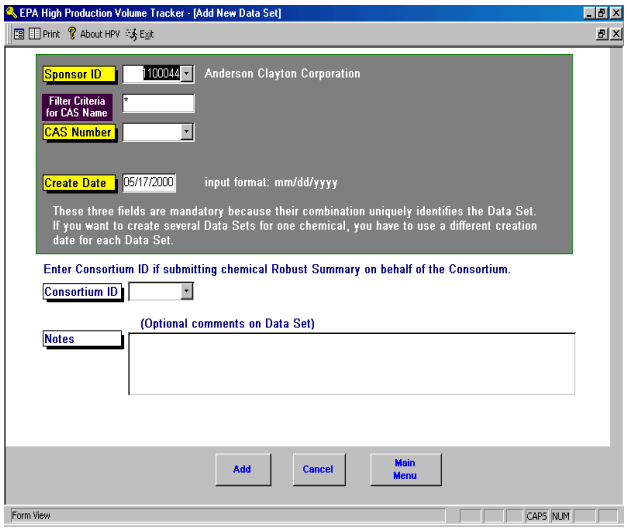

Figure 12

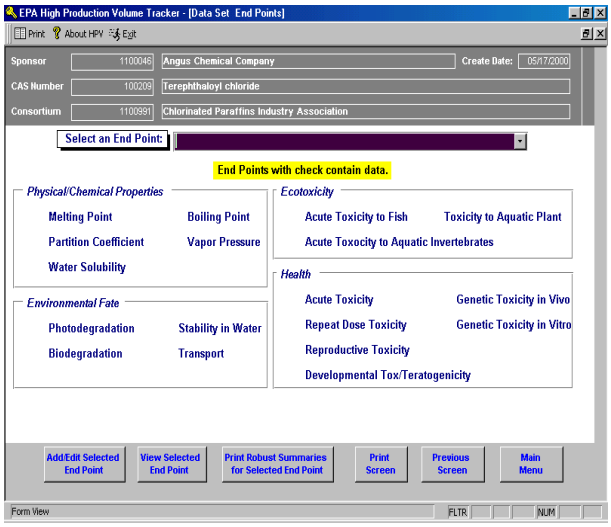

Figure 13

2. Searching Data - This option allows you to search available data sets within the database.

To obtain a listing of all or selected data sets entered in your database, click on the “Search Data Set” button from the Main Menu page. Displayed will be the search data set screen, where a specific CAS Number, Consortium, date range, or combination of the three may be entered to list the data set(s) within your database. The screen may also be left blank to obtain a complete list of all data sets entered. Once the search criteria have been specified, click the “List Data Sets”button at the bottom of the screen (Figure 14).

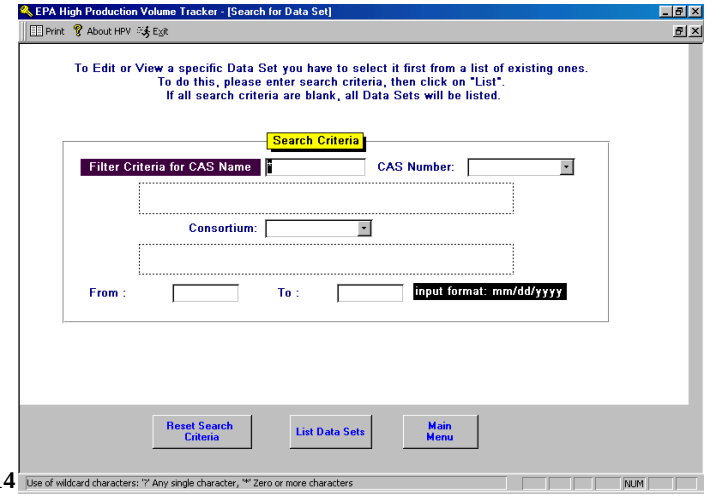

Figure 14

A listing of all data sets entered in your database is displayed by *Sponsor, CAS Number, Consortium and Create Date*. Select the desired data set by clicking in the left margin next to the data set to be edited, viewed, revised or printed. These functions plus the ability to add, delete, print the data set(s), return to the previous screen and main menu are made available via the push-button options at the bottom of the screen (Figure 15).

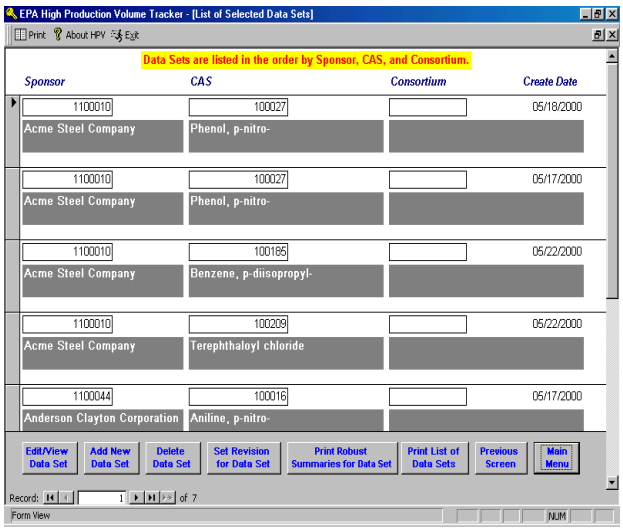

Figure 15

Figure 12

3. Mandatory Field Check - allows the submitter to check all files for completeness of certain “mandatory” fields. Mandatory fields are those identified as important pieces of information that make up a “minimum” robust summary. The mandatory field check button does not prevent either the saving or sending of database files which are “incomplete”; it is simply a reminder to the submitter that not all mandatory fields were populated for a given endpoint.

4. Create EPA Export Files - allows submitters to export the data entered to .txt files to be compressed (zipped) and submitted to EPA for incorporation into a central database repository. You should export data to .txt file format for two reasons: (1) .txt files can be translated by most word processing systems; and (2) .txt files require less space if transmitting via email and/or diskette.

Select “Create EPA Export Files” from the Main Menu (Figure 16). From the export screen displayed, click on the “Continue Exporting Data” button. When the “Exporting Destination Screen” is displayed (Figure 17), follow the screen instructions provided and click on the “Export” push button to generate and export the data entered to .txt file format.

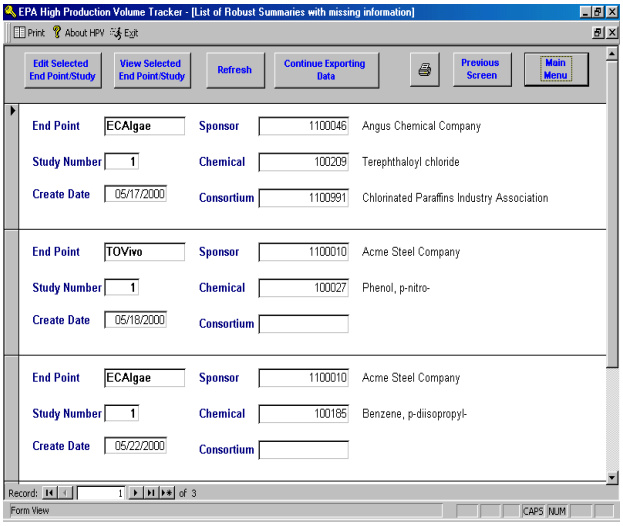

Figure 16

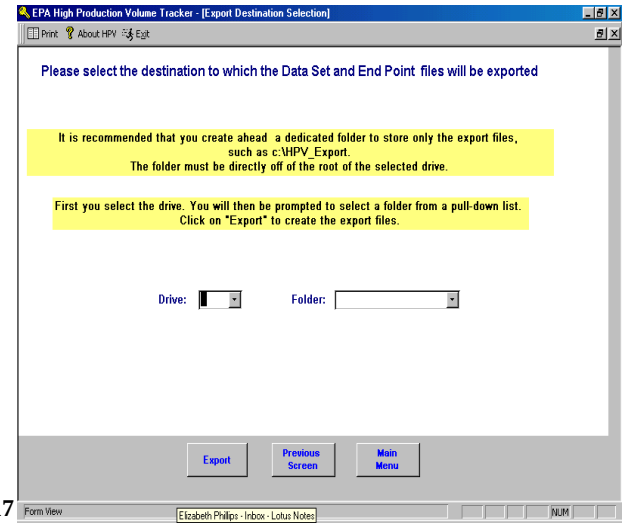

Figure 17

All data by endpoint will be exported to the *drive:\folder* created according to the instructions provided. Each file is identified by the endpoint name with the date/time stamp showing when the file was created. Example (this file is an acute toxicity to fish database file):

ECFishTx_05182000101837.txt

5. Import Chemical, Consortia and Company (left buttons on the bottom of Figure 18)- allows users to import updated HPV chemical, consortia and company lists. This feature will be useful in the future when updated lists can be downloaded from the EPA website.

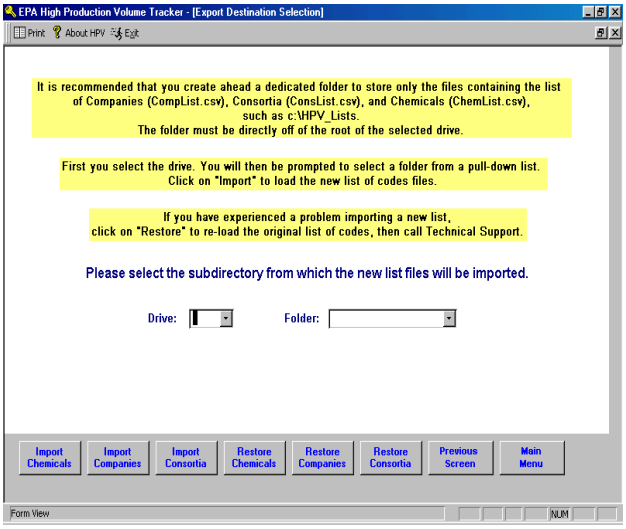

Figure 18

6. Exit EPA HPV Tracker - Exit the database

B. Entering Data - General Information

Most of the data entry fields are self-explanatory. It is important to note that during data entry, help notes have been provided to assist in identifying the type of information required for the particular data entry field. Help notes are also shown on the status line at the bottom of the screen.

1. Creating a Data Set

The first step to creating a data set for a Robust Summary submission is to define the key identifiers for the data set. These include *Sponsor, CAS Number, and Create Date* (creation date) which are discussed below in more detail.

From the Main Menu page, click on the “Add Data Set” button. Displayed is the data entry screen to establish the unique identifier for your Data Set (Figure 19). The information provided on this screen will be unique and consistent for each study summary throughout the session of data entry.

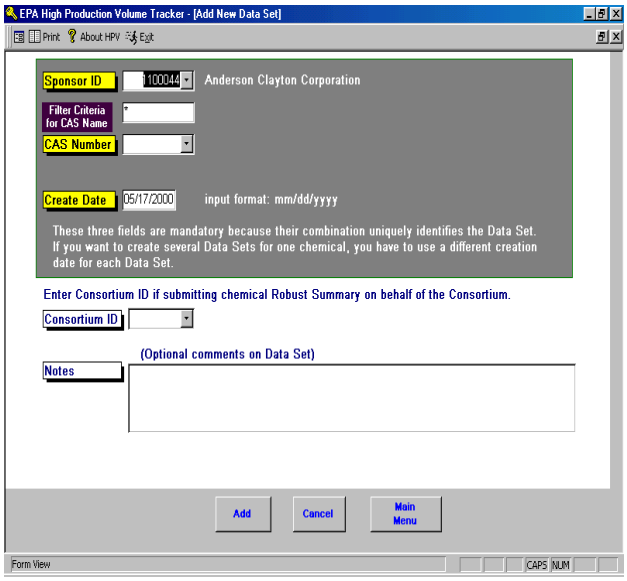

Figure 19

The key identifier and details on how to populate them are:

• Sponsor ID (Sponsor Identification) - Click on the down arrow to display a predefined drop-down list of all the chemical companies that have sponsored a chemical in the U.S. HPV Challenge Program. The list is presented alphabetically by company. Simply click on your company and the database will automatically display the name of the company next to the ID number, which is an EPA-assigned company number.

• Filter Criteria for CAS Name - An asterisk in this field will display a complete list of all the HPV chemicals on the U.S. list when you click on the down arrow at the CAS Number field. Entering the wildcard '?'for any single character, or '*' for zero or more characters, restricts the list in the CAS Number field to the HPV chemical with the specified string.

• CAS Number (Chemical Abstract Service Number) - Click on the down arrow to display a predefined drop-down list of all the HPV chemicals on the U.S. list, in numerical CAS number order. Choose the chemical for which you will be entering data. The CAS No. and the name will automatically appear.
• Create Date - System-generated and automatically populated.

• Consortium ID (Consortium Identification) - If submitting data on behalf of a Consortium, click on the down arrow to display a predefined drop-down list of all the consortia approved for participation in the HPV Challenge Program. The number listed is the EPA-assigned number for a given consortium.

• Notes - Let's the submitter provide notes to eventual users.

2. The Endpoint Summary Screen

The next step to entering data for your Robust Summary is to identify an endpoint. Click on the "Add" button on the bottom of the key identifier screen (Figure 19) to display the endpoint summary screen to select an endpoint (Figure 20). Note that the header section of this page lists a non-editable version of the *Sponsor, CAS Number, Chemical Name, Consortium* (if applicable), *and the Creation Date* defined in the "Create Data Set" step (Figure 20). Below it are two sections: the large, white- background ("endpoint section") listing the Screening Information Data Set (SIDS) endpoints that make up the basic information of the U.S. HPV Challenge Program, and the bottom gray area ("options section") with six push buttons identifying continued database functions.

• Endpoints Section - The Endpoints section lists the SIDS endpoints which need to be fulfilled for the U.S. HPV Challenge Program. The endpoints are divided into four major categories: physicochemical properties, environmental fate, ecotoxicity, and health. At the very top of the "Endpoint Section" is a field titled "Select an Endpoint". An endpoint **MUST** be selected from the drop-down list provided to allow data entry.

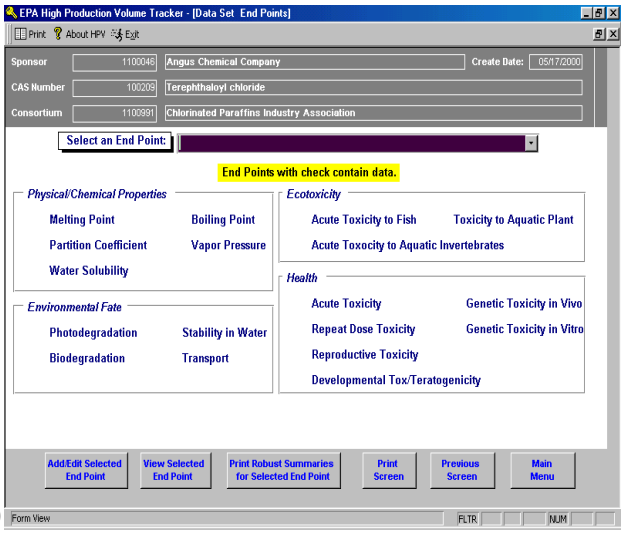

Figure 20

Click on the down arrow to display a drop-down listing of the endpoints. Select the particular endpoint being reported. An endpoint template is provided for the purposes of adding/editing, viewing, or printing robust summaries for the selected endpoint.

Once an endpoint template has been accessed for data entry of a particular endpoint, when you return to the endpoint screen for that data set, a red check mark will appear next to the endpoint(s) in which data has been entered (Figure 21).

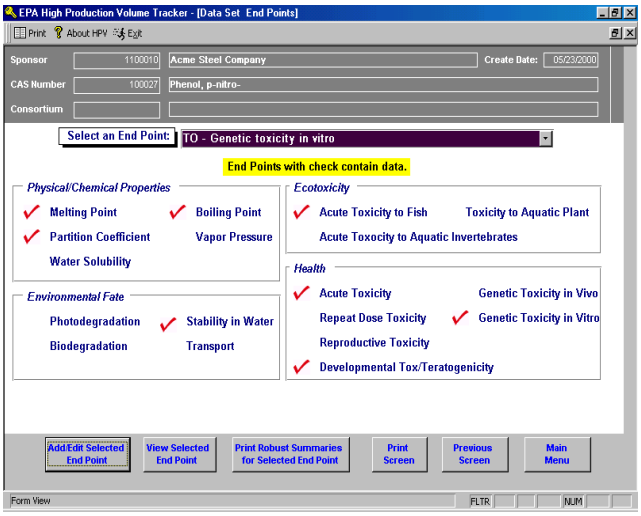

Figure 21

• Options Section - This section applies the push-button feature to allow the submitter to continue to the next phase of data entry for the selected endpoint. **Note**: An endpoint **MUST** be selected to continue data entry.

• Add/Edit and View Selected Endpoint - will display a standard endpoint data entry template and allow the submitter to add new data or edit and view existing data for an endpoint of the defined data set.

• Print Robust Summary for Selected Endpoint - this option first displays a screen view of the completed Robust Summary. A menu bar with the page set, printer, magnifier and close icons are available at the top of the screen.

• Print Screen, Previous Screen and Main Menu options are self-explanatory.

V. ENTERING DATA - DETAILS

A. Introduction

The purpose of each endpoint template is to allow the user to enter information that adequately describes the type of study conducted and the outcome of the study. For the most part, self-explanatory prompts are provided and most technically knowledgeable users should have no trouble filling out the appropriate template. However, because not all the guidance could be put into the software, the information presented below should help a user present the appropriate information.

Each template covers the information items that should be included in a robust study summary for a specific SIDS endpoint. Robust study summaries are intended to provide sufficient information to allow a technically qualified person to make an independent assessment of a given study without having to go back to the full study report. Robust study summaries should represent the key study(s) on which the assessment of each SIDS endpoint is based. It is generally expected that the most adequate, reliable, and relevant study (i.e., the key or critical study) for each SIDS endpoint will be clearly identified and reported to the fullest level of the template. In cases where the study is considered inadequate, this should be clearly marked together with the reasons.

Studies describing “non-SIDS” endpoints, but which support conclusions for one of those endpoints (for example, information from "non-SIDS endpoints" such as carcinogenicity or epidemiology studies to support the repeat dose endpoint) may be described in the General Remarks field of the endpoint to which the information is proposed to apply.

B. The Individual Endpoint Screen

Following is step-by step guidance on filling in the appropriate information for each of the SIDS endpoints listed on the “Endpoint Page.”

Upon entering any endpoint template, the push-button icons described below will be displayed on the top tool bar. Below that will be the non-editable header section containing the unique key identifier information defined at the start of your data entry.

- Left and right arrows - these buttons allow you to navigate the “records” within that endpoint. For example, if you are submitting four repeat dose toxicity studies, this feature allows you to view each separate study record by pressing the appropriate directional arrow. The studies will be assigned a study number in the order they were entered.

- Binoculars button - once the information has been entered and saved, this feature allows a search of text entered within the summary.

• Check Completeness and Save - Checks the endpoint study for completeness of all mandatory fields and saves the study to the database.

• Add a new study - allows entry of multiple studies of the same endpoint for the same data set.

• Delete Current Study - deletes the current study from the database.

• Printer - first displays a screen view of the completed Robust Summary. A menu bar with the page set, printer, magnifier and close icons is available at the top of the screen.

• Previous Screen and Main Menu options are self-explanatory.

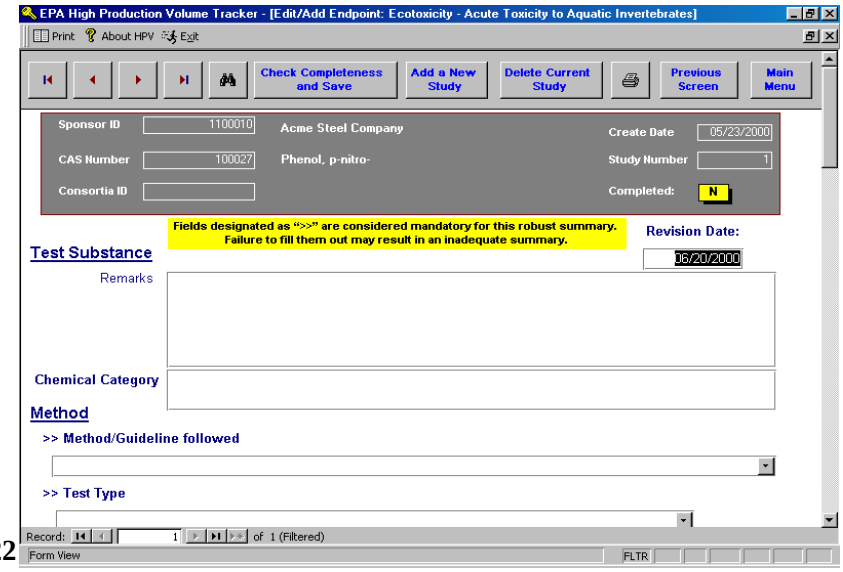

Figure 22

C. Fields Common to All Endpoints

All endpoint templates have fields which need to be filled in with the information that would adequately summarize (a "robust summary") the experiment/study/estimation method presented. General guidance on developing robust summaries has already been made available on EPA's website (*Draft Guidance on Developing Robust Summaries*) which is available online at : http://www.epa.gov/opptintr/chemrtk/robsumgd.htm

The various field types include controlled vocabulary fields, text fields, numeric fields, and remarks fields. Controlled vocabulary fields force the user to pick from a list of choices from a pull-down menu. The text and numeric fields will only accept either text or numbers, and the bottom status bar will let you know the size of the field you are in. Remarks fields are expected

to be used to further explain the content of a particular section, much as is done in the "discussion" portion of a publication in an academic journal. Remarks fields are not limited in size, and will expand to contain whatever information is entered. In preparing the Remarks Fields, you may cut and paste from other existing documents.

Before talking about each individual endpoint, you need to be familiar with some information/fields that are the same for all endpoints. First, the “Study number” field in the header portion of the screen (the gray area at the top) is automatically set to “1" when you first enter an endpoint template. This means the study/information you enter is for the first study to be described under this endpoint. If you want to add another study, you click “Add a New Study” button at the top, and this number will automatically change to “2," and so on.

Second, all endpoint tables have the following common fields:

Test Substance Section:

- Test Substance Remarks - Refers to the identity of the chemical used in the study or estimation. The following information should be included in the test substance remarks: purity, additives, solvent carrier, contaminants, and chemical formula. Most of the time, the chemical tested will be the HPV chemical. However, if it is not, then an explanation of its relevance to the HPV chemical must be provided here.
- Chemical Category - If this chemical AND endpoint are being used to support a category submission, name the category here. The sponsor chooses the name of the category - PLEASE BE CONSISTENT EACH TIME IT IS ENTERED. If the chemical is not part of a category submission, leave this field blank.

Method Section

- Method - This section refers to the methodologies used to conduct the study. A pull-down menu is provided. If the method used is not listed, simply type in the method used. If there were deviations from the stated method, more information should be included in the "Remarks on Method" field (see below). There may also be situations in which a single study addresses several endpoints, such as with a study that follows the OECD combined repeat dose/reproduction/developmental Test Guideline 421. In this example, if this single study was to be the key one for each of these endpoints, then three separate robust study summaries would be prepared, one for each endpoint all pointing to the same study.
- GLP - Were Good Laboratory Practices followed in the study? A pull-down menu is provided.
- Year - insert the 4-digit year in which the study ended.
- Remarks on Method - This field allows for needed comments and remarks such as test protocol deviations and their potential effect on the study outcome. Endpoint-specific details for this section are provided when more information is necessary (see endpoint-by-endpoint guidance below).

Results Section

- Results Remarks - Describe additional information that may be needed to confirm data reliability and relevance. Unexpected results could be further explained in this field (for example, results seen were due to the complex nature of the test substance, deviations in protocol, etc.). Endpoint-specific details for this section are provided when more information is necessary (see endpoint-by-endpoint guidance below).

Conclusions Section

- Concluding Remarks - This field can be used to further explain the context of a particular section, much as is done in the "Discussion" portion of a publication in academic journals. Also, if the submitter disagrees with the study author's conclusions, both views should be expressed here.

Data Quality Section

- Reliability - This field can be used to denote the adequacy of data at the discretion of the person preparing the robust summary. You may also want to refer to the guidance document on data adequacy, available on the internet at: http://www.epa.gov/opptintr/chemrtk/datadfin.htm
- Reliability Remarks - Add comments about how the reliability of data was determined, or add other related remarks.

Reference Section

- Reference Remarks - This field is for the full citation of the report on which the robust study summary is based. Also, additional full references that are supportive may be listed.

General Information

- General Remarks - Here the submitter can add any information that doesn't fit into any of the other fields.

D. Endpoint by Endpoint Guidance

Guidance is presented only for sections that require explanations/fields different from the common fields discussed above. For example, unless there is some specific fields/guidance for the Method Section for an endpoint, it will not be presented below.

In many cases, a field has a box with a down-turned arrow in it. Clicking on this will show a menu that offers a pre-determined variety of choices for the submitter.

HELPFUL HINTS:

(1) For endpoints requiring "temperature units be entered in ºC" and a drop-down list is not provided, generate the degree (º) symbol as follows: Turn "Num Lock" - [On], Hold Down [ALT] key, Press [0186] on numbers key pad, Release [ALT] key.

(2) Cutting and Pasting Text: Follow the general instructions for cutting text in accordance with the application being used. To paste text, place the cursor in the appropriate "Remarks" box and Press [CTRL] and "V" simultaneously.

PHYSICOCHEMICAL Endpoints

Melting Point

Results Section

Precision - Insert mathematic symbol to describe the measured value (options are =, <, >, ≤, ≥) unless a range is given, in which case this field should be left blank.
Melting point value - Measured numeric value reported to the nearest whole degree. Units must be provided in the "unit" field below. The lower value is listed in this field.
Upper value - The upper value is listed in this field, otherwise leave blank.
Unit - Temperature units used. Preferably in ºC.
Decomposition - Does substance decompose during melting point test? If yes, list temperature in ºC in the Results Remarks field; otherwise indicate as no, or ambiguous.
Sublimation - Does sublimation occur? If yes, list temperature in ºC ; otherwise indicate no, or ambiguous.
Results Remarks - If the substance is a liquid, note here that the value reported is a freezing point.

Boiling Point

Results Section

Precision - Insert mathematic symbol to describe the measured value (options are =, <, >, ≤, ≥) unless a range is given, in which case this field should be left blank.
Boiling point value - Measured numeric value reported to the nearest whole degree. Units must be provided in the "unit" field below. The lower value is listed in this field.
Upper value - The upper value is listed in this field, otherwise leave blank.
Unit - Temperature units used. Preferably in ºC.
Pressure - Pressure level at which boiling point was determined. If other than standard pressure conditions (i.e., 760 mm Hg), provide numeric value and units here. If standard pressure, leave blank.
Pressure Unit - List pressure unit (preferably in mm Hg).

Decomposition - Does substance decompose during boiling point test? If yes, list temperature in ºC in the Results Remarks field; otherwise indicate as no, or ambiguous.

Vapor Pressure

Results Section

Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥) unless a range of values is given, in which case this field should be left blank.
Vapor pressure value - Measured or estimated numeric value reported to four significant figures. Units must be provided in the "unit" field below. If a range is presented, the lower value is listed in this field.
Upper value - If a range of values is given, the upper value is listed in this field, otherwise leave blank.
Unit -Pressure units used. Pressure unit used (preferably mm Hg)
Temperature - Provide the temperature (with units, preferably in ºC) used in the experiment or assumed in the model, if estimated.
Decomposition - Does substance decompose at the temperature used to measure the vapor pressure? If yes, list temperature in ºC in the Results Remarks field; otherwise indicate as no, or ambiguous.

Partition Coefficient

Results Section

Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥) unless a range of values is given, in which case this field should be left blank.
Value for Log Pow - Measured or estimated numeric value reported to two decimal places (e.g., 7.04). If a range is presented, the lower value is listed in this field.
Upper value - If a range of values is given, the upper value is listed in this field, otherwise leave blank.
Temperature - Provide the temperature (with units, preferably in ºC) used in the experiment or assumed in the model, if estimated.
Results Remarks - Note whether the test substance is surface active, dissociative, and its water solubility.

Water Solubility

Results Section

Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥) unless a range of values is given, in which case this field should be left blank.

Water Solubility Value - Measured or estimated numeric value reported to two significant figures. Units must be provided in the "unit" field below. If a range is presented, the lower value is listed in this field.
Upper value - If a range of values is given, the upper value is listed in this field, otherwise leave blank.
Unit - Mass per unit volume (preferably mg/L).
Temperature - Provide the temperature (with units, preferably in ºC) used in the experiment or assumed in the model, if estimated.
Solubility category - Based on value/range of results, choose one of the following text descriptions: Very soluble (>10,000 mg/L); soluble (1000-10,000 mg/L); moderately soluble (100-1,000 mg/L); slightly soluble (0.1-100 mg/L); insoluble (<0.1 mg/L).
pH Value - Note pH at which the solubility was determined.
pKa - Note pKa (if applicable). This is the pH where 50% of the material dissociates.
Results Remarks - Note whether a vehicle was used or precipitation was observed.

ENVIRONMENTAL FATE AND PATHWAY Endpoints

Photodegradation

Method Section
Light Source - State source of light used, for example, sunlight, xenon lamp, or other.
Light Source Spectrum in nm - Wavelength of light source (in nanometers).
Relative Intensity - If artificial light is used, state relative intensity based on intensity of sunlight.
Absorption Spectrum of Substance -(1) max (maximum wavelength at which absorption of light is greatest), (2) max (absorption of substance at maximum), and (3) 295 (absorption at 295 nm).
Method Remarks - Include the following as appropriate: test medium (air, water, soil, other - specify); duration of test; positive/negative controls (identity and concentration).
Results Section
Concentration value - Initial concentration of test substance used. Place numeric value here and units in next field (if more than one dose, list highest here and report others in Method Remarks).
Unit - Unit value (depending on test medium, either mg/L, mg/cubic meter, or mg/kg).
Temperature - Provide the temperature (with units, preferably in ºC) used in the experiment or assumed in the model, if estimated.
Direct Photolysis Precision - Insert mathematic symbol to describe the measured/estimated value for direct photolysis (options are =, <, >, ≤, ≥).
Direct photolysis - Measured or estimated half life. Units must be provided in the "unit" field below.
Direct photolysis unit - Time in minutes, hours, days, or months.

Indirect Photolysis Precision - Insert mathematic symbol to describe the measured/estimated value for indirect photolysis (options are =, <, >, ≤, ≥).
Indirect photolysis - Measured or estimated half life. Units must be provided in the "unit" field below.
Indirect photolysis unit - Time in minutes, hours, days, or months.
Sensitizer - If indirect photolysis is assessed, list name of sensitizer chemical (e.g., water, ozone).
Sensitizer concentration - Concentration of sensitizer used with units, e.g., mg/L.
Sensitizer unit - Unit value (depending on test medium, either mg/L, mg/cubic meter, or mg/kg).
Rate constant - If radical is used as sensitizer, provide rate constant in cubic cm/molecule/second.
Breakdown products - Are there breakdown products? Yes/no/unknown. If yes, describe in Results remarks.
Results Remarks - If available, describe the following: percent degradation results other than half lives (e.g., the % degraded after time t); quantum yield (e.g., total recovery at end of test as a fraction (0-1.0)); and any breakdown products.

Stability in Water

Method Section
Test type - PLEASE CHOOSE ABIOTIC.
Remarks for method - Note the following: duration (days) of test; positive/negative controls (identity and concentration.); analytical procedures used to measure test substance loss.
Results Section
Nominal concentration - Amount of chemical (preferably in mg/L) ADDED TO the test system
Measured concentration - Amount of chemical MEASURED in the test system using named analytical procedure.
Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Hydrolysis Result - Measured or estimated half life. If half life not estimated or provided, see Results Remarks.
Unit - Time in minutes, hours, days, months.
pH value List pH condition for reported results.
Temperature - Temperature at which test was run, preferably in ºC.
Breakdown Products - Are there breakdown products? Yes/no/unknown. If yes, describe in Results remarks.
Results Remarks - If provided in report, state percent degradation at a specified pH and temperature ºC after a specified time and the nature of breakdown products (if found).

Transport Between Environmental Compartments

Method Section

Test type -Level I, II or III fugacity model. The EQC Level III model is strongly recommended and my be downloaded from the Trent University website (www.trentu.ca/envmodel).

Remarks for method -Detail the model used (title, version and date) and the input parameters (chemical-specific, environmental conditions) as necessary.

Results Section

Media - State partitioning results of the substance to various environmental media (e.g., 40% in air, 20% in water, ...) for each level of model run (e.g., I, II and/or III; Level III is recommended).

Distribution Concentration - Model outputs of chemical concentration by environmental medium.

Results Remarks - Please note the following if reported in model output: overall persistence or residence time, adsorption coefficient, desorption, and volatility.

Biodegradation

Method Section

Test type -Note whether aerobic or anaerobic conditions.

Contact Time -Length of time substance is incubated in test medium (days).

Inoculum - Name microorganism(s) used (choose from pull-down menu list).

Remarks for method - Please note the following as appropriate: (1) for studies using inoculated test medium such as ready and inherent biodegradability tests, note the concentration and source of the inoculum; (2) for studies using grab samples of natural media (water, soil, sediment), note the source of the sample, time of collection, environmental temperature at the time of collection, conditions during transport of sample to the laboratory, and any other noteworthy observations relating to the collection site; (3) concentration of test chemical, vehicle used, pre-acclimation conditions, temperature of incubation (in ºC); dosing procedure; sampling frequency; (4) controls and blank system used; (5) analytical method used to measure biodegradation; (6) method of calculating measured concentrations (i.e., arithmetic mean, geometric mean, etc.)

Results Section

Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥) unless a range of values is given, in which case this field should be left blank.

Degradation value - Percent ultimate degradation (ready; inherent); amount of test material degraded as a percentage of the starting amount; half-life or rate constant. IN THE RESULTS REMARKS FIELD, PLEASE NOTE WHICH OF THESE DESCRIPTORS REPRESENTS THE NUMBER ENTERED HERE. If a range is presented, the lower value is listed here.

Upper value - If a range of values is given, the upper value is listed in this field, otherwise leave blank.
Time Frame - List the number of hours, days or months to which the results are applicable. Only put the number here, the time units will be entered separately in the next field.
Time units - Units for reported degradation time (hours, days or months).
Breakdown Products - Are there breakdown products? Yes/no/unknown. If yes, describe in Results remarks.
Results Remarks - Describe additional information that may be needed, e.g. lag time, observed inhibition, excessive biodegradation, excessive standard deviation, time required for 10% degradation, total degradation at test's end, and any breakdown products found. If half-life or rate constant listed above, indicate what kinetic model (e.g., first order or pseudo first order) was used to calculate the reported value.

ECOTOXICITY Endpoint(s)

Acute Toxicity to Fish

Method Section
Test type -static, semi-static, flow-through
Species - Name of species tested (pull-down menu provided).
Analytical monitoring - Analytic method used to measure chemical in water and limit of detection.
Exposure Period - Length of test in time units (generally hours).
Statistical method - Cite statistical method used.
Remarks for method - Please note the following as appropriate: (1) organism information: age, length, weight, loading, pretreatment; (2) test conditions: dilution water source, dilution water chemistry (hardness, alkalinity, pH, TOC, TSS, salinity), how stock and test solution were prepared, flow-through rate, vehicle/solvent and concentrations, stability of test chemical solutions, exposure vessel type (e.g., size, headspace, sealed, aeration, lighting, # per treatment), number of replicates, fish per replicate, water chemistry (D.O., pH) in control and one concentration where effects were observed; (3) test temperature range; and (4) method of calculating mean measured concentrations (arithmetic mean, geometric mean, etc.)
Results Section
Nominal concentration - Amount of chemical (preferably in mg/L) added to the test system (list all concentrations in the test, separated by commas).
Measured concentration - Amount of chemical measured in the test system (list all concentrations in test separated by commas).
Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Endpoint type - LC50, LC0, etc.
Endpoint value - Concentration associated with endpoint type. (Place numeric value here and units below.)

Concentration type - Note whether reported endpoint value is measured or nominal concentration.
Units used - Mass per unit volume (preferably mg/L)
Endpoint time - Length of time for endpoint type above (48, 72, or 96 hours). Note: use longest time here, and note other results in results remarks.
Statistical results - Note statistical results, with appropriate p value.
Results Remarks - Discuss if effect concentration is greater than water solubility of the test chemical. Include the following, if available: biological observations, table showing cumulative mortality, lowest test substance concentration causing 100% mortality, mortality of controls, abnormal responses. Reference substances (if used) - results. Any observations, such as precipitation, that might cause a difference between measured and nominal values.

Acute Toxicity to Aquatic Plants

Method Section
Test type - Static, semi-static, flow-through
Species - Name of species tested (pull-down menu provided).
Endpoint - What effect(s) were measured/assessed (e.g., number of cells/ml, area under the curve, growth rate, etc.)
Analytical monitoring - Analytic method used to measure chemical in water and limit of detection.
Exposure Period - Length of test in time units (generally hours).
Statistical method - Cite statistical method used.
Remarks for method - Include the following as appropriate: (1) organism information; laboratory culture, method of cultivation, controls; (2) test conditions: test temperature range, growth/test medium chemistry (hardness, alkalinity, pH, TOC, TSS, dissolved oxygen, salinity, EDTA), dilution water source, exposure vessel type (e.g., size, headspace, sealed, aeration, # per treatment), water chemistry (DO, pH) in at least one replicate of each concentration (at start and end of the test), stock solutions preparation (vehicle, solvent, concentrations), light levels and quality during exposure, number of replicates, concentrations, (3) method of calculating mean measured concentrations (i.e. arithmetic mean, geometric mean, etc.)
Results Section
Nominal concentration - Amount of chemical (preferably in mg/L) added to the test system (list all concentrations in the test, separated by commas).
Measured concentration - Amount of chemical measured in the test system (list all concentrations in test separated by commas).
Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).

Endpoint type - For example, ErC50, ErL50, EbC50, EbL50, EC10-CD, EL10-CD, EC50-CD, EL50-CD, EL90-CD, EC90-CD, EC0, or EL0.
Endpoint value - Concentration associated with endpoint type. (Place numeric value here and units below.)
Concentration type - Note whether endpoint value is measured or nominal concentration.
Units used - Mass per unit volume (preferably mg/L)
Endpoint time - Length of time for endpoint type above (48, 72, or 96 hours). Note: use longest time here, and note other results in results remarks.
NOEC precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
NOEC - List no observed effect concentration. (Place numeric value here and units below.)
Unit used - NOEC Units as mass per unit volume (preferably mg/L).
NOEC concentration type - Note whether NOEC is measured or nominal concentration.
NOEC effect(s) assessed - NOEC effect(s) assessed (e.g., growth rate, biomass,).
LOEC precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
LOEC - List lowest observed effect concentration. (Place numeric value here and units below.)
Unit used - LOEC Units as mass per unit volume (preferably mg/L).
LOEC concentration type - Note whether LOEC is measured or nominal concentration.
LOEC effect(s) assessed - LOEC effect(s) assessed (e.g., growth rate, biomass).
Response of control group - Was it satisfactory? Yes/No or unknown.
Statistical results - Note statistical results, with appropriate p value.
Results Remarks - Discuss if effect concentration is greater than the water solubility. Describe additional information including the following: note whether cells removed prior to measurement; biological observations; cell density at each flask at each measuring point, growth curves, percent biomass/growth rate inhibition per concentration

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Acute Toxicity to Aquatic Invertebrates

Method Section
Test type - Static, semi-static, flow-through
Species - Name of species tested (pull-down menu provided).
Analytical monitoring - Analytic method used to measure chemical in water and limit of detection.
Exposure Period - Length of test in time units (generally hours).
Statistical method - Cite statistical method used.
Remarks for method - Describe the following as appropriate: (1) organism information: source, supplier, any pretreatment, breeding method, age at study initiation, control group; (2) test conditions; stock solutions preparation (vehicle, solvent, concentrations) and stability, test temperature range, exposure vessel type (e.g., size, headspace, sealed, aeration, # per treatment), dilution water source, dilution water chemistry (hardness, alkalinity, pH, TOC,

TSS, salinity, Ca/Mg ratio, Na/K ratio), lighting (quality, intensity and periodicity), water chemistry (D.O., pH) in control and at least one concentration where effects were observed; (3) endpoints assessed (i.e., immobilization); (4) test design (number of replicates, individuals per replicate, concentrations); (5) method of calculating mean measured concentrations (e.g., arithmetic mean, geometric mean, etc.)

Results Section

Nominal concentration - Amount of chemical (preferably in mg/L) added to the test system (list all concentrations in the test, separated by commas).

Measured concentration - Amount of chemical measured in the test system (list all concentrations in test separated by commas).

Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).

Endpoint type - LC50, LC0, etc.

Endpoint value - Concentration associated with endpoint type. (Place numeric value here and units below.)

Concentration type - Note whether endpoint value is measured or nominal concentration.

Units used - Mass per unit volume (preferably mg/L)

Endpoint time - Length of time for endpoint type above (48, 72, or 96 hours). Note: use longest time here, and note other results in results remarks.

Statistical results - Note statistical results, with appropriate p value.

Results Remarks - Discuss if effect concentration is greater than water solubility of the test chemical. Include the following, if available: biological observations, table showing cumulative mortality, number immobilized as compared to the number exposed, concentration response with 95% confidence limits, cumulative immobilization, lowest test substance concentration causing 100% mortality, mortality/response of controls, abnormal responses. Reference substances (if used) - results. Any observations, such as precipitation, that might cause a difference between measured and nominal values.

HEALTH Endpoint(s)

Acute Toxicity (Mammals)

Method Section

Species - Name of species tested (pull-down menu provided).

Strain - Mammal strain, e.g., Sprague-Dawley rat, Swiss Webster mouse.

Sex - males only, females only, or both sexes used in test.

Number of animals per dose - self-explanatory.

Vehicle - If vehicle was used, identify and provide the volume used.

Route of administration - Oral, dermal, inhalation, or other (e.g., subcutaneous, intravenous).

Remarks for method - Include the following as appropriate: age of animals used; doses (OECD Test Guidelines 420, 423, and 425 do not provide dose levels, so these must be

described in detail); doses per time period; volume administered or concentration; post dose observation period; exposure duration (for inhalation studies).

Results Section

Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).

Acute lethal value - Measured or estimated numeric value, for example, LD50 or LC50. Units must be provided in the "unit" field below.

Unit - Unit used (preferably mg/kg).

Deaths per dose - Number of deaths observed at each dose level.

Results Remarks - Including the following, if available: time of death (provide individual animal time if less than 24 hours after dosing); description, severity, time of onset and duration of clinical signs at each dose level; necropsy findings, including doses affected, severity and number of animals affected; potential target organs (if identified in the report); if both sexes tested, results should be compared.

Genetic Toxicity (in vivo)

Method Section

Test type - Type of Assay (e.g., cytogenetic, dominant-lethal, or micronucleus).

Species - Name of species tested (pull-down menu provided).

Strain - Mammal strain, e.g., Sprague-Dawley rat, Swiss Webster mouse.

Sex - males only, females only, or both sexes used in test.

Number of animals per dose - self-explanatory.

Route of administration - oral, dermal, inhalation, other (subcutaneous, intravenous).

Doses - List all doses used in test, separated by commas, and their units.

Exposure Period - if more than one dose, list frequency (both amount and frequency)

Statistical method - Cite statistical method used.

Remarks for method - Include the following as appropriate: age at study initiation, vehicle, duration of test, frequency of treatment, sampling times and number of samples, control groups and treatment, clinical observations performed (clinical pathology, functional observations, etc.), organs examined at necropsy (macroscopic and microscopic), criteria for evaluating results (for example, cell types examined, number of cells counted in a mouse micronucleus test), criteria for selection of maximum tolerated dose.

Results Section

Effects on mitosis - Effect on mitotic index or PCE/NCE ratio by dose level and by sex.

Genotoxic effects - Positive, negative, unconfirmed, or equivocal (pull-down menu).

Statistical results - Note statistical results, with appropriate p value.

Results Remarks - Include the following, if available: mortality at each dose level by sex, mutant/aberration/mPCE/polyploidy frequency, as appropriate; description, severity, time of onset and duration of clinical signs at each dose level and sex; body weight changes by dose and sex; food/water consumption changes by dose and sex.

Genetic Toxicity (in vitro)

Method Section

Test type - E.g., reverse mutation assay, gene mutation study, cytogenetic assay, mammalian cell gene mutation assay, cytogenetic assay.
System of testing - Bacterial, non-bacterial.
Species - Name species/cell line used.
Metabolic activation - List the following: species and cell type; quantity; induced or not induced (if induced, name inducer).
Concentration - List all concentrations used in test, separated by commas (include units).
Statistical method - Cite statistical method used.
Remarks for method - Include the following as appropriate: (1) test design: number of replicates; frequency of dosing; positive and negative control groups and treatment; number of metaphases analyzed for chromosomal studies; (2) describe solvent/vehicle, if used, and concentration; (3) if follow-up study, describe how different from original; (4) criteria for evaluating results (e.g. cell evaluated per dose group)

Results Section

Result - Ambiguous, negative, or positive.
Cytotoxic concentration - Note concentration that is cytotoxic and whether it is with or without metabolic activation.
Genotoxic effects - Unconfirmed, dose-response, equivocal; with or without metabolic activation.
Statistical results - Note statistical results, with appropriate p value.
Results Remarks - Note test-specific confounding factors such as pH, osmolarity, whether substance is volatile, water soluble, precipitated, etc., particularly if they affect the selection of test concentrations or interpretation of the results. Provide at a minimum qualitative descriptions of elements where dose effect related observations were seen. Frequency of reversions/mutations/aberrations, polyploidy as appropriate; mitotic index

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Repeat Dose Toxicity

Method Section

Species - Name of species tested (pull-down menu provided).
Strain - Mammal strain, e.g., Sprague-Dawley rat, Swiss Webster mouse.
Sex - males only, females only, or both sexes used in test.
Number of animals per dose - self-explanatory.
Route of administraton - oral, dermal, inhalation, other (subcutaneous, intravenous).
Exposure Period - Duration of study in days (for example, 28 days, 90 days).
Frequency of treatment - Number of doses per day, week, etc. (this is particularly relevant for inhalation experiments – 6 hrs/day, 5 days/week).
Doses - List all doses used in test separated by commas (include units).

Control group - Concurrent controls: Yes, no, or unknown.
Post-observation period - Length of time animals observed after last dose.
Statistical method - Cite statistical method used.
Remarks for method - Include the following as appropriate: age at study initiation; note whether vehicle used and concentration/volume; satellite groups and reasons they were added; clinical observations performed and frequency (clinical pathology, functional observations, etc.); organs examined at necropsy (macroscopic and microscopic).

Results Section

NOAEL Precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
NOAEL Dose - Dose that establishes the no observed adverse effect level (NOAEL).
Unit - Unit used (mg/l, mg/kg, ppm, etc.)
NOAEL effect(s) - Effect assessed (e.g., decrease in body weight, organ histopathology)
LOAEL precision - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
LOAEL - Dose that establishes lowest observed adverse effect level (LOAEL).
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
LOAEL effect(s) - Effect assessed (e.g., decrease in body weight, organ histopathology)
Actual dose received by dose level by sex - Actual dose received by dose level by sex, if known.
Toxic response - A brief narrative describing toxic response or effects, by dose level.
Statistical results - Note statistical results, with appropriate p value.
Results Remarks - Provide at a minimum qualitative descriptions where dose effect related observations were seen: body weight; food/water consumption; description, severity, time of onset and duration of clinical signs; ophthalmologic findings incidence and severity; hematological findings incidence and severity; clinical biochemistry findings incidence and severity; mortality and time to death; gross pathology incidence and severity; organ weight changes; and histopathology incidence and severity.

Reproductive Toxicity

Method Section

Test type - fertility, one-generation, two-generation, other (pull-down menu).
Species - Name of species tested (pull-down menu provided).
Strain - Mammal strain, e.g., Sprague-Dawley rat, Swiss Webster mouse.
Sex - males only, females only, or both sexes used in test.
Number of animals per dose - self explanatory.
Route of administraton - oral, dermal, inhalation, other (subcutaneous, intravenous).
Exposure Period - Duration of study in days (from day 0 to end).
Frequency of treatment - Number of doses per day, week, etc. (this is particularly relevant for inhalation experiments – 6 hrs/day, 5 days/week).
Doses - List all doses used in test, separated by commas (include units).

Control Group - concurrent controls: Yes, no, or unknown.
Premating exposure period for female - Premating exposure period for female. Number of days and doses to females prior to mating (P and F1 as appropriate).
Premating exposure period for male - Premating exposure period for male. Number of days and doses to males prior to mating (P and F1 as appropriate).
Statistical method - Cite statistical method used.
Remarks for method - Include the following as appropriate: number, age, sex per dose for P, F1 and F2, if appropriate; note whether vehicle used and concentration/volume; dosing schedules and pre and post dosing observations periods for P, F1 and F2, if appropriate; mating procedures (M/F ratios per cage, length of cohabitation, proof of pregnancy); standardization of litters (yes/no and if yes, how and when). Parameters assessed for P and F1 as appropriate; clinical observations performed and frequency (clinical pathology, functional observations, etc.); estrous cycle length and pattern (number of days spent in each phase); sperm examination (epididymal or vas sperm, concentration, motility, morphology). Parameters assessed for F1 and F2, as appropriate; clinical observations performed and frequency (weight gain, growth rate, etc.). Other information: for example, anogenital distance, if performed. Organs examined at necropsy (macroscopic and microscopic).

Results Section

Parental Precision/NOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Parental NOAEL - NOAEL dose for parent.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
Parental NOAEL effect(s) - Effect(s) assessed.
Parental Precision/LOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Parental LOAEL - LOAEL dose for parent.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
Parental LOAEL effect(s) - Effect(s) assessed.
F1 Precision/NOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
F1 NOAEL - NOAEL dose for F1 generation.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
F1 NOAEL effect(s) - Effect(s) assessed.
F1 Precision/LOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
F1 LOAEL - LOAEL dose for F1 generation.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
F1 LOAEL effect(s) - Effect(s) assessed.
F2 Precision/NOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
F2 NOAEL - NOAEL dose for F2 generation.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
F2 NOAEL effect(s) - Effect(s) assessed.

F2 Precision/LOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
F2 LOAEL - LOAEL dose for F2 generation.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
F2 LOAEL effect(s) - Effect(s) assessed.
Actual dose received by dose level and sex - Actual dose received by dose level by sex, if known.
Parental/F1 data - Parental data and F1 as appropriate (toxic response/effects with NOAEL value). At a minimum, provide qualitative descriptions of dose-related observations.
Offspring data - Offspring toxicity F1 and F2, as appropriate (toxic response/effects with NOAEL value). At a minimum, provide qualitative descriptions of dose-related observations.
Statistical results - Note statistical results, with appropriate p value.
Results Remarks - Include the following qualitative descriptions of dose-related observations: (1) Parental and F1 data; body weight; food/water consumption; description, severity, time of onset and duration of clinical signs; fertility index (pregnancies/matings); precoital interval (w/number of days until mating and number of estrous periods until mating); duration of gestation (calculated from day 0 of pregnancy); gestation index (live litters/pregnancies); changes in lactation; changes in estrus cycles; effects on sperm; hematological findings incidence and severity; clinical biochemistry findings incidence and severity; mortality; gross pathology incidence and severity; number of implantations; number of corpora lutea (recommended); ovarian primordial follicle counts; organ weight changes; histopathology incidence and severity; (2) Offspring (F1 and F2) data: litter size and weights; sex and sex ratios; viability index (pups surviving 4 days/total births); post natal survival until weaning; effects on offspring (grossly visible abnormalities); postnatal growth, growth rate; vaginal opening (F) or preputial separation (M). Other observations, for instance anogenital distance, if measured. Organ weights; gross pathology.

Developmental Toxicity

Method Section
Species - Name of species tested (pull-down menu provided).
Strain - Mammal strain, e.g., Sprague-Dawley rat, Swiss Webster mouse.
Sex - males only, females only, or both sexes in test.
Number of animals per dose - self-explanatory.
Route of administraton - oral, dermal, inhalation, other (subcutaneous, intravenous).
Dosing regimen (days of gestation) - Gestation days females were exposed to the test substance (e.g., days 6-15 (in rats)), where day 0 is first day of pregnancy.
Frequency of treatment - Number of doses per day, week, etc. (this is particularly relevant for inhalation experiments – 6 hrs/day, 5 days/week).
Doses - List all doses used in test separated by commas (include units).
Control Group - concurrent controls: Yes, no, or unknown.

Statistical method - Cite statistical method used.
Remarks for method - Include the following as appropriate: number, age, sex per dose; note whether vehicle used and concentration/volume, clinical observations performed and frequency. Mating procedures (M/F ratios per cage, length of cohabitation, proof of pregnancy); parameters assessed during study (maternal and fetal); organs examined at necropsy (macroscopic and microscopic).

Results Section

Maternal Precision/NOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Maternal NOAEL - NOAEL dose for maternal animals.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
Maternal NOAEL effect(s) - Effect(s) assessed.
Maternal Precision/LOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Maternal LOAEL - LOAEL dose for maternal animals.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
Maternal LOAEL effect(s) - Effect(s) assessed.
Developmental Precision NOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Developmental NOAEL - NOAEL dose for offspring.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
Developmental NOAEL effect(s) - Effect(s) assessed.
Developmental Precision LOAEL - Insert mathematic symbol to describe the measured/estimated value (options are =, <, >, ≤, ≥).
Developmental LOAEL - LOAEL dose for offspring.
Unit - Unit used (mg/l, mg/kg, ppm, etc.).
Developmental LOAEL effect(s) - Effect(s) assessed
Actual dose received by dose level and sex - Actual dose received by dose level by sex, if known.
Maternal data with dose level - Maternal data with dose level (with NOAEL value). At a minimum, provide qualitative descriptions of dose-related effects: mortality and day of death; number pregnant per dose level; number aborting; number of resorptions, early/late if available; number of implantations; pre- and post-implantation loss, if available; number of corpora lutea (recommended); duration of pregnancy; body weight; food/water consumption; description, severity, time of onset and duration of clinical signs; hematological findings incidence and severity; clinical biochemistry findings incidence and severity; gross pathology incidence and severity; organ weight changes, particularly effects on total uterine weight; histopathology incidence and severity.
Fetal data with dose level - Fetal data with dose level (with NOAEL value). At a minimum, provide qualitative descriptions of dose-related effects: litter size and weights; number viable (number alive and number dead); sex ratio; postnatal growth (depending on protocol); postnatal survival (depending on protocol); grossly visible abnormalities, external, soft tissue and skeletal abnormalities.

Statistical results - Note statistical results, with appropriate p value.
Results Remarks - Note any other results of significance not otherwise mentioned above under maternal/fetal remarks sections.

VI. COMPILING AND SUBMITTING FILES TO EPA

A. Compiling Data from Multiple Users.

IMPORTANT NOTE: Because all data is editable at this point, it is strongly recommended that individuals maintain of copy of their individual entries **[epa_hpvv.mde]** until final document(s) are developed.

The application must be installed on each workstation that will be used to access the database.

As an individual completes the data entry for a specific endpoint(s) segment, the databases .mde file **[epa_hpvv.mde]** must be forwarded to the next user via e-mail, diskette, or placed on a shared network drive. The next submitter will replace the original .mde file in their work folder or directory created during application installation. Launch the application as normal **[Start\Programs\EPA HPV Tracker\EPA HPV Tracker]**. The database will utilize the transmitted .mde file **[epa_hpvv.mde]** which will include all the data from previous entries. Begin entry of data for responsible endpoints.

The application **does** allow the basic cut and paste feature of text from other documents.

A more advanced feature to combine information for the same chemical, CAS Number and sponsor from multiple users will be incorporated into the next version of the application.

B. Submitting Data to EPA.

Perform Mandatory Field Check on data entered and save data set. Select the "Check Completeness and Save" push button from the tools bar of the endpoint template screen. You will be prompted as to whether all the mandatory data have been entered. If data are missing, review endpoint template to verify that all fields designated as mandatory by the ">>" symbol have data and the data is of the correct type for that data field. Missing data does not preclude the system from saving information entered thus far, but allows the submitter the opportunity to complete any mandatory fields that may have been overlooked.

The final step in submitting Robust Summaries via the EPA HPV Chemical Challenge Tracker is to export all data from your internal database to a .txt file format as illustrated and explained earlier in Section IV.A.4, Figures 16 and 17.

VII. EPA CONTACTS:

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VIII. GLOSSARY

Data Set	Derived from the IUCLID database and defined as the unit in which information is stored within the database.
IUCLID	International Uniform Chemical Information Database. An Oracle database designed by European Commission, European Chemicals Bureau for use all over Europe.
OECD	Organization for Economic Co-operation and Development
SIDS	Screening Information Data Set
Endpoint	A generic term for the parameter assessed/measured. The endpoints in the U.S. HPV Challenge Program are: melting point, boiling point, vapor pressure, partition coefficient, water solubility, photodegradation, hydrolysis (stability in water), biodegradation, transport/distribution (model estimate), acute toxicity to aquatic species (fish, invertebrates and plants), and toxicity to animals (acute, repeat dose, genetic effects, and reproductive/developmental effects).
Template	The term used for the computer format and structure for each SIDS endpoint. Templates have been structured to allow for computerised data entry of the important information that would constitute a robust study summary for that endpoint.
Mandatory Field(s)	Any field annotated with a ">>" symbol. Mandatory fields are those identified as important pieces of information that make up a "minimum" robust summary. The mandatory field check button does not prevent either the saving or sending of database files which are "incomplete"; it is simply a reminder that not all mandatory fields were populated for a given endpoint.
Remark Fields	A free text field used to further explain the content of a particular section, much as is done in the "discussion" portion of a publication in an academic journal.
Controlled Vocabulary	Predefined list which force the submitter to select from the choices provided.
Robust Study Summary	Information captured in this database which is intended to provide sufficient information to allow a technically qualified person to make an independent assessment of a given study without have to go back to the full study report.